DETAILED ACTION

Claims 1-28 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 16 and 19, and claims 20 and 21 (in part, as they read on claim 19), drawn to a protein of SEQ ID NO: 4, or homolog thereof; a method of manufacturing a pharmaceutical using said protein; and a pharmaceutical comprising said protein.

Group II, claim(s) 8-10, 17 and 18, and claims 20 and 21 (in part, as they read on claim 18) drawn to a nucleic acid encoding a protein of SEQ ID NO: 4; a method of using the nucleic acid to make a pharmaceutical composition; and a pharmaceutical composition comprising said nucleic acid.

Group III, claim(s) 11-12, drawn to an antibody against a protein of SEQ ID NO: 4.

Group IV, claim(s) 13-14, drawn to a method to determine the tendency of falling ill with type 1 diabetes, comprising determining a mutation in genomic DNA.

Group V, claim(s) 15, drawn to a method to determine the tendency of falling ill with type 1 diabetes, comprising determining increased/decreased expression of RNA.

Group VI, claim(s) 22-24, drawn to a transgenic non-human mammal, where the germ and somatic cells contain a nucleic acid which encodes a protein with the amino acid sequence of SEQ ID NO: 2, or homolog thereof.

Group VII, claim(s) 25-27, drawn to a method of using a transgenic non-human animal, where the germ and somatic cells contain a nucleic acid which encodes a protein with the amino acid sequence of SEQ ID NO: 2, or homolog thereof..

Group VIII, claim(s) 28 (in part, as it reads on claims 13-14), drawn to a kit for determining the tendency of falling ill with type 1 diabetes by determining a mutation in genomic DNA.

Group IX, claim(s) 28 (in part, as it reads on claim 15), drawn to a kit for determining the tendency of falling ill with type 1 diabetes by determining RNA expression.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups I-IX do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a protein of SEQ ID NO: 4, or a homolog thereof, which is not shared with any of the other groups. The products of Groups II, III, VI, VIII and IX do not have a significant shared structure with the protein product of Group I. Further, the methods of Groups IV, V and VII do not make or use the product of Group I.

Accordingly, Groups I-IX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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